OCT 7 - 2005

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InScope™ Multi-Clip Applier
510(k) Summary of Safety and Effectiveness

Company
INSCOPE
A Division of Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Kimberly Shoemaker, RAC
Manager, Regulatory Affairs

Date Prepared:
July 15, 2005

Name of Device
Trade Name: InScope™ Multi-Clip Applier
Classification Name: Clip Applier/Endoscopic Clipping Device

Predicate Devices:
Trade Name:
Syntheon, LLC: Endoscopic Multi-Fire Clip Applier
Olympus Optical Co., Ltd.: Rotatable Clip Fixing Device HX-5/6-1

Device Description
The InScope™ Mult-Clip Applier is a sterile, single patient use, disposable instrument capable of attaching clips to the mucosal lining of the gastrointestinal (GI) tract. The clips are used to create hemostasis and/or tissue approximation. The distal, flexible portion of the applier is designed to work with a flexible endoscope having a minimum working channel diameter of 3.2 mm. Two opposing jaws grasp tissue via a manually activated lever on a proximal handle. Once the closure lever is latched, a firing mechanism is manually activated, which deploys a titanium clip over the target tissue. The device is supplied preloaded with four (4) titanium clips.

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Indications for Use

The InScope Multi-Clip Applier is indicated for use with an endoscope to place clips in the gastrointestinal (GI) tract for the purpose of:

- Endoscopic marking,
- Hemostasis for:
  - Mucosal and submucosal defects < 3 cm
  - Bleeding ulcers
  - Arteries < 2 mm
  - Polyps < 1.5 cm in diameter
  - Diverticula in the colon
- Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
- Closure of GI tract luminal perforations < 20 mm in patients where an alternative to surgery is required.

Technological Characteristics

The InScope™ Multi-Clip Applier does not have the identical indication statements as the predicate devices, but the differences noted do not alter the intended therapeutic/diagnostic effect.

Performance Data

Results of bench and preclinical testing demonstrate that performance of the InScope Multi-Fire Clip Applier is substantially equivalent to the predicate devices in regards to hemostasis, clip retention and lack of tissue damage upon clip placement (tissue remains viable).

A literature review in combination with the preclinical data demonstrates the use of the InScope Multi-Clip Applier for closure of gastrointestinal perforations, fistulas, anastomotic leaks and for control of bleeding diverticula is not likely to raise any new or increased risks to safety and effectiveness compared to risks experienced with similar marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Kimberly Shoemaker, RAC
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
CINCINNATI OH 45242-2839

Re: K051950
Trade/Device Name: InScope™ Multi-Clip Applier
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Product Codes: MND and FHN
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: KOG
Regulatory Class: II
Dated: September 23, 2005
Received: September 26, 2005

Dear Ms. Shoemaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K051950

Indications for Use

510(k) Number (if known): K051950
Device Name: InScope™ Multi-Clip Applier
Indications for Use:

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- Closure of GI tract luminal perforations < 20 mm in patients where an alternative to surgery is required.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051950